

**REMARKS**

**I. Status of the Claims**

Applicants direct the Examiner's attention to the Preliminary Amendment, filed November 28, 2001. *See* Form PTO-1390. After entry of the Preliminary Amendment, claims 1-11, 13, 15-17, 19, 22 and 26-28 are pending. Claims 12, 14, 18, 20-21, 23-25, 29-56 were previously canceled without prejudice or disclaimer.

**II. The Restriction Requirement and Applicant's Provisional Election**

The Examiner required restriction, under 35 U.S.C. §§ 121, 372, between Groups I to XXX as these inventions or groups of inventions allegedly are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In response, Applicants hereby elect, with traverse, Group I, claims 1-7, 9, 11, 15-17, 22 and 26-28, drawn to a polynucleotide, a polypeptide, and methods of use, only in so far as they relate to SEQ ID NO:1.

Applicants note that the non-elected method claims should be rejoined, as a matter of right, upon allowance of a product claim. *See* MPEP § 821.04.

**III. In Accordance With Office Practice, The Examination Of Claims To Ten Polynucleotide Sequences Does Not Create An Undue Burden**

Applicants draw the Examiner's attention to Section 803.04 of the Manual of Patent Examining Procedure. While contending that nucleotide sequences that encode different proteins "constitute independent and distinct inventions" the Commissioner has decided to "permit a reasonable number of such nucleotide sequences to be claimed in a single application" so as to "further aid the biotechnology industry in protecting its intellectual property." See *id.* To this end, the Patent Office "determined that normally ten sequences

constitute a reasonable number for examination purposes" and that that number does not create "an undue burden on the Office." Id. Indeed, the Office states that "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Id. Accordingly, the Examiner's contention that Groups I to VI are "distinct from the other" and, therefore, subject to restriction, is not consistent with Office practice.

Indeed, under the "Examples of Nucleotide Sequence Claims" subsection of Section 803.04, the Office states that "[O]nly the *ten* nucleotide sequence selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom *will* be examined" (emphasis added).

For this reason, Applicants further traverse the restriction requirement. Applicants contend that Groups II to VI (claims 1-7, 9, 11, 15-17, 22 and 26-28), drawn to the polynucleotides encoding a protein comprising the amino acid sequences of SEQ ID NO: 2-6, should be examined alongside the polynucleotides of Group I. Accordingly, Applicants kindly request that the Examiner rejoin Groups I to VI and examine together these ten polynucleotides.

#### IV. Conclusion

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should be charged to our Deposit Account.

Respectfully submitted,

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